

application. However, claims 1 through 9 and 13 through 15 have been finally rejected.

Applicants respectfully request reconsideration of the application in light of the remarks set forth herein.

35 U.S.C. § 103(a) Obviousness Rejections

Each of pending claims 1 through 9 and 13 through 15 stands rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over Magruder et al. (U.S. Patent No. 5,630,808) or over Magruder et al. taken in combination with Theeuwes et al. (U.S. Patent No. 4,088,864). A rejection under Section 103(a), however, is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that the teachings of the references cited in the Office Action, whether taken alone or in combination, fail to provide evidence sufficient to properly establish the *prima facie* obviousness of any of the pending claims. Thus, Applicants respectfully request that the rejections of claims 1 through 9 and 13 through 15 under Section 103 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The examiner bears the burden of establishing these three criteria based on the prior art, and, significantly, this burden can be met “only by showing some **objective teaching** in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis added).

Claims 1 through 9, 13 and 15 are rejected in the Office Action as being unpatentable over Magruder et al. However, Applicants respectfully submit that the teachings of Magruder et al. fail to establish the *prima facie* obviousness of any of claims 1 through 9, 13 or 15. In particular the teachings of Magruder et al. fail to teach or suggest each of the limitations included in the rejected claims. Claim 1 is an independent claim that recites a dosage form comprising “an outer wall defining an interior compartment,” “at least one laser formed orifice in the outer wall,” and “a barrier layer disposed between the outer wall and the interior compartment in at least a region corresponding to the at least one exit orifice wherein the barrier layer comprises a material that allows the barrier layer to remain intact during formation of the at least one laser formed exit orifice.” Claims 2 through 9, 13 and 15 depend either directly or indirectly from claim 1, and therefore incorporate each of the limitations included in claim 1. In contrast to the subject matter recited in these claims, however, the delivery system taught in Magruder et al. does not include an outer wall defining an interior compartment with a barrier layer disposed between the outer wall and the interior compartment, wherein (1) the barrier layer is positioned in at least a region corresponding to the at least one exit orifice and (2) the barrier layer comprises a material that allows the barrier layer to remain intact during formation of the at least

one laser formed exit orifice.” In addition, the Magruder et al. fails to even suggest a delivery device that includes a barrier layer as recited in the rejected claims.

It is asserted in the Office Action that the second wall section included in the delivery device taught by Magruder et al. serves as a barrier layer as defined by the rejected claims. However, as is appreciable by reference to, for example, FIG. 9 and FIG. 10 of Magruder et al., the second wall section is not positioned in at least a region corresponding to an exit orifice provided in the delivery device. In fact, the second wall section included the device taught by Magruder et al. is positioned at the end of the device opposite the end that includes the exit orifice. Moreover, the teachings of Magruder et al. fail to teach or suggest that the material used to create the second wall section should be chosen such that the second wall section would remain intact during formation of the exit orifice if the second wall section was positioned in the region corresponding to the exit orifice. Therefore, Magruder et al. fails to teach or suggest each of the limitations included in any of claims 1 through 9, 13 and 15, and Applicants respectfully request that the rejection of these claims under Section 103 as being unpatentable over Magruder et al. be withdrawn.

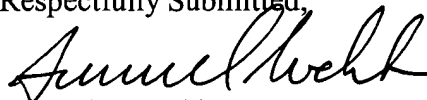
Claims 1 through 9, and 13 through 15 are rejected in the Office Action under Section 103 as unpatentable over Magruder et al. in view of Theeuwes et al. However, Applicants respectfully submit that the combined teachings of Magruder et al. and Theeuwes et al. fail to establish the *prima facie* obviousness of any of claims 1 through 9 or 13 through 15. In particular, the combined teachings of Magruder et al. and Theeuwes et al. fail to teach or suggest a dosage form comprising “an outer wall defining an interior compartment,” “at least one laser

formed orifice in the outer wall,” and “a barrier layer disposed between the outer wall and the interior compartment in at least a region corresponding to the at least one exit orifice wherein the barrier layer comprises a material that allows the barrier layer to remain intact during formation of the at least one laser formed exit orifice.” As has already been detailed, the teachings of Magruder et al. fail to teach or suggest a dosage form having a barrier layer as defined in the rejected claims, and the combination of the teachings of Magruder et al. with the teachings of Theeuwes et al. does not remedy this deficiency. Theeuwes et al. teaches an apparatus and method for making passageways in pills using lasers, but the teachings of Theeuwes et al. are void of any teaching or suggestion regarding a dosage form having a barrier layer as recited in the rejected claims. Thus, the combination of Magruder et al. and Theeuwes et al. fails to teach or suggest each of the limitations included in the rejected claims, and Applicants respectfully request that the rejection of claims 1 through 9 and 13 through 15 over the combined teachings of Magruder et al. and Theeuwes et al. be withdrawn.

CONCLUSION

Claims 1 through 9 and 13 through 15 are believed to be in condition for allowance, and a notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



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